4. PROGRAM REGULATIONS

401.401: Introduction

130 CMR 401.000 contains regulations governing independent clinical laboratory services under MassHealth. All independent clinical laboratories participating in MassHealth must comply with the regulations of the Division governing MassHealth, including, but not limited to, Division regulations at 130 CMR 401.000 and 130 CMR 450.000.

401.402: Definitions

The following terms used in 130 CMR 401.000 have the meanings given in 130 CMR 401.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 401.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 401.000 and 450.000.

Authorized Prescriber—any individual who is authorized under state law to prescribe drugs.

Bulk Purchase—a single purchase of the same laboratory services (one or more tests) to be uniformly and concurrently performed on a minimum of 40 specimens.

Hospital Laboratory—a clinical laboratory that is owned and operated by a hospital, which is licensed by the Massachusetts Department of Public Health and is an approved Medicare provider.

Clinical Laboratory—a facility, that conducts microbiological, serological, chemical, hematological, biophysical, radiobioassay, cytological, immunohematological, immunological, pathological, or other examinations of materials derived from the human body, to provide information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of any disease.

Independent Clinical Laboratory—a freestanding clinical laboratory that is not affiliated with a hospital.

Panel Test—any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics:

(1) the group of tests is designated as a panel by the clinical laboratory performing the tests; or
(2) the group of tests is performed by the clinical laboratory at a usual and customary fee that is lower than the sum of that laboratory's usual and customary fees for the individual tests in that group.

Referring Laboratory—a clinical laboratory that forwards specimens to a testing laboratory for specific tests that cannot be performed by the referring laboratory.

Testing Laboratory—a clinical laboratory that performs one or more tests on a specimen forwarded by a referring laboratory.

Usual and Customary Fee—the lowest fee in effect at the time of service, other than a fee offered for a bulk purchase, that is charged by an independent clinical laboratory for any laboratory service, including profile tests, specified in the fee schedule or by the laboratory.

401.403: Eligible Members

(A) (1) MassHealth Members. The Division covers independent clinical laboratory services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
(2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

401.404: Provider Eligibility

An independent clinical laboratory must be a participant in MassHealth on the date of service in order to be eligible for payment.

(A) In-State Providers. To be eligible for participation as a MassHealth provider, an independent clinical laboratory must be:
(1) located and doing business in the Commonwealth of Massachusetts;
(2) certified as an independent clinical laboratory by HCFA, based on the criteria set forth in the Clinical Laboratory Improvement Amendments (CLIA) of 1988; and
(3) licensed by the Massachusetts Department of Public Health.

(B) Out-of-State Providers. A provider that does not meet the requirements of 130 CMR 401.404(A)(1) and (3) may participate in MassHealth only if the provider is licensed in its own state and meets the requirements of 130 CMR 401.404(A)(2) and 450.109.

(C) Multiple Facilities. When two or more independent clinical laboratories have the same director or owner, whether or not the laboratories have different names, each laboratory must enroll separately with MassHealth and have its own MassHealth provider number.

401.405: Laboratory Services Provided outside of Massachusetts

When provided out of state, independent clinical laboratory services are reimbursable only if:

(A) the member is temporarily out of state and requires clinical laboratory services under the circumstances described in 130 CMR 450.109; or

(B) the Division determines that the independent clinical laboratory services required by the member are not available from any laboratory in Massachusetts.

(130 CMR 401.406 through 401.409 Reserved)

401.410: Covered Services

MassHealth covers independent clinical laboratory services necessary for the diagnosis, treatment, and prevention of disease, and for the maintenance of the health of MassHealth members, subject to all restrictions and limitations described in the Division's regulations at 130 CMR 401.000 and 450.000.

401.411: Noncovered Services

(A) The Division does not pay for the following services:

(1) routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue);

(2) laboratory tests associated with male or female infertility;

(3) calculations (for example, red cell indices, A/G ratio, creatinine clearance), and ratios calculated as part of a profile;

(4) tests performed for experimental or investigational purposes, or that are themselves experimental or investigational; and

(5) tests performed for forensic purposes or any purpose other than those described in 130 CMR 401.410(A), including but not limited to:

(a) tests performed to establish paternity;

(b) tests performed pursuant to or in compliance with a court order (for example, monitoring for drugs of abuse); and

(c) post-mortem examinations

(B) The Division will not pay an independent clinical laboratory for a service that the laboratory is not certified by HCFA to perform.

(130 CMR 401.412 through 401.414 Reserved)

401.415: Specimen Referral

(A) If an independent clinical laboratory cannot perform a requested test, it may refer the specimen to another laboratory that can perform the test. The testing laboratory must be

(1) an independent clinical laboratory or a hospital laboratory participating in MassHealth; and

(2) located within the borders of Massachusetts, unless there is no other laboratory in Massachusetts that performs the requested test.

(B) The referring laboratory must inform the prescriber of the name and address of the testing laboratory.

(C) The testing laboratory must inform the referring laboratory of the test results.

(D) The referring laboratory may not bill the Division for tests performed by the testing laboratory.

(E) Under no circumstances may both the referring and testing laboratories bill for the same procedure performed on the same specimen.

401.416: Request for Laboratory Services

(A) The independent clinical laboratory may not bill for a service until it has received a written request to perform that specific service from the authorized prescriber. Each request to perform a specific service must be signed in ink by the authorized prescriber. Stamped or preprinted signatures are not acceptable. Any independent clinical laboratory billing for a service must maintain such request in its records to be made available to the Division upon the Division's request. If the laboratory that billed for the service cannot produce the original request, the Division may deny or recover payment for all services the laboratory provided based on that request.

(B) If a laboratory refers a specimen to a testing laboratory, the referring laboratory must forward to the testing laboratory the original request to perform the service, signed by the authorized prescriber. The testing laboratory must maintain such request in its records in accordance with 130 CMR 401.416(A).

401.417: Laboratory Records

Both referring and testing laboratories must keep a record of each specimen and test result for at least four years from the date on which the results were reported to the prescriber. If an independent clinical laboratory cannot produce the record to substantiate a MassHealth claim, the Division may deny or recover payment for that claim. The laboratory record must contain the following information:

(A) the identification number of the specimen;

(B) the name or any other means of confidentially identifying the person from whom the specimen was taken;

(C) the name of the prescriber and, if applicable, the referring laboratory that submitted the specimen;

(D) the date on which the specimen was collected by the prescriber or laboratory;

(E) the date on which the specimen was received in the laboratory;

(F) the condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, or turbid);

(G) the test performed;

(H) the date on which the test was performed;

(I) the results of the test and the date of reporting; and

(J) the name and address of the laboratory to which the specimen was referred, if applicable.

401.418: Maximum Allowable Fees

(A) The Division of Health Care Finance and Policy (DHCFP) determines the maximum allowable fees for independent clinical laboratory services. The maximum allowable payment for a service is the lowest of the following:

(1) the amount listed in the applicable DHCFP fee schedule;
(2) the independent clinical laboratory's usual and customary fee; or
(3) the amount that would be recognized under 42 U.S.C. s. 13951(h) for tests performed for a person with Medicare Part B benefits.

(B) The maximum allowable payment is full compensation for the laboratory service and any related administrative or supervisory duties in connection with the service, regardless of where the service was provided.

(C) In no event may an independent clinical laboratory bill for more than its usual and customary fee for the service.

401.419: Individual Consideration

(A) Some tests listed in Subchapter 6 of the *Independent Clinical Laboratory Manual* are designated "I.C.," an abbreviation for individual consideration. A fee has not been established for these services. Payment for an individual-consideration service is determined by the Division's professional advisers, based on the laboratory's description of the test, which must be included with the claim.

(B) If a test is not listed in Subchapter 6 of the *Independent Clinical Laboratory Manual*, an independent clinical laboratory may submit a claim by using the appropriate "unlisted test" service code. Payment for an unlisted test is determined by individual consideration, based on the laboratory's description of the test, which must be included with the claim.

(C) The Division considers the following factors when determining the appropriate payment for an individual-consideration service:

(1) the amount of time required to perform the procedure;
(2) the degree of skill required to perform the procedure;
(3) policies, procedures, and practices of other third-party payers;
(4) prevailing medical-laboratory ethics and accepted custom of the medical-laboratory community; and
(5) other standards and criteria as may be adopted by DHCFP.

401.420: Panel Tests

An independent clinical laboratory may not bill or be paid separately for a test included in a panel test when a panel test has been performed by that laboratory or requested by an authorized prescriber.

401.421: Quality Assurance and Provider Review

The Division conducts reviews of providers and administers quality-control programs to ensure that MassHealth members are receiving high-quality medical services. An independent clinical laboratory must maintain its own quality-control program and successfully participate in one or more proficiency testing programs that cover all Medicare-certified specialties and subspecialties of the laboratory. The laboratory must make available to the Division the results of the proficiency testing programs upon request or during an on-site visit.

REGULATORY AUTHORITY

130 CMR 401.000: M.G.L. c. 118E, §§ 7 and 12.